



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-741/S-018

Novo Nordisk Pharmaceuticals, Inc.  
Attention: Barry Reit, Ph.D.  
Vice President, Regulatory Affairs  
100 College Road West  
Princeton, NJ 07540

Dear Dr. Reit:

Please refer to your supplemental new drug application dated June 12, 2003, received June 13, 2003, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Prandin® (repaglinide) Tablets, 0.5 mg, 1 mg, and 2 mg.

We acknowledge receipt of your submission dated August 5, 2003.

This supplemental new drug application provides for changes to the **CLINICAL PHARMACOLOGY** section, **Drug-Drug Interactions** subsection, and **PRECAUTIONS** section, **Drug Interactions** subsection of the package insert.

We completed our review of this application as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling for the package insert submitted on August 5, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-741/S-018." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.  
Director  
Division of Metabolic and Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure (draft submitted August 5, 2003)

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/s/

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David Orloff

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